



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,174	02/07/2002	John C. Reed	8014-014 US	2991

32301 7590 11/28/2006

CATALYST LAW GROUP, APC
9710 SCRANTON ROAD, SUITE S-170
SAN DIEGO, CA 92121

EXAMINER

ANGELL, JON E

ART UNIT	PAPER NUMBER
----------	--------------

1635

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,174

Applicant(s)

REED ET AL.

Examiner

Jon Eric Angell

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-9,11-23,25-28,76,77 and 142-163 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,4-9,11-14 and 26-28 is/are allowed.
- 6) ☒ Claim(s) 15-23,25,76,77 and 142-163 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Action is in response to the communication filed on 9/11/2006.

The amendment filed 9/11/2006 is acknowledged and has been entered.

Claims 1, 4-9, 11-23, 25-28, 76, 77, 142-163 are currently pending in the application and are addressed herein.

1. Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-23, 25, 76, 77, 142-163 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Art Unit: 1635

MPEP §2163.06 notes:

If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).

MPEP §2163.02 teaches that:

Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.

MPEP §2163.06 further notes:

When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure.

The claims (15, 16, 76, 142 and 148) have been amended to include the new limitation that the sequence is greater than 700 base pairs in length (claims 15, 76, 142), 701-1000 base pairs (claim 16), or 701 base pairs to 2.5 kB in length (claim 148). Applicants indicate that support for these new limitation can be found on page 30 (paragraphs 1 and 4). However, page 30, paragraphs 1 and 4 recite:

"... Thus, if a nucleic acid sequence has the requisite sequence identity to SEQ ID NO:1, or a subsequence thereof, it also is a polynucleotide sequence of the invention. In various aspects, the sequence is less than about 50 Kb, 25 Kb, 10 Kb, 5 Kb or 2.5 Kb. In additional aspects, the sequence is between about 2.5-1.0 Kb, 1.0-0.5 Kb, 0.25-0.1 Kb and 100-15 base pairs. In yet other aspects, the sequence is selected from SEQ ID NO:1; SEQ ID NO:1 where one or more T's are U's; nucleic acids complementary to these sequences and subsequences of the aforementioned sequences at least 15 base pairs long."; (paragraph 1) and,

Art Unit: 1635

“Sequences included in the invention are those that hybridize to exemplary Bcl-B sequence set forth in Example 1 (SEQ ID NO:1). Such sequences may be the entire length of the sequence, or may be fragments. For example, in various embodiments, the sequence that hybridizes has a length of about 12-30, 30-50, 50-100, 100-250, 250-500, 500-1000, 1000-2500, 2500-5000 or 5000-10000 base pairs. Such sequences are also distinct from Accession no. AA098865.” (paragraph 4)

Nowhere in these paragraphs, can explicit support for the specific limitations “700 base pairs in length”, “701-1000base pairs” or “701 base pairs to 2.5 kB in length” be found.

Furthermore, the entire specification was carefully searched but nowhere in the specification could proper support for the indicated limitations be found.

The disclosure indicated on page 30 does not provide proper support for “700 base pairs in length”, “701-1000 base pairs” or “701 base pairs to 2.5 kB in length” because the indicated paragraphs only discloses lengths that may include 700 or 701 nucleotides and up to 1kB or 2.5kB, the specification does not appear to explicitly disclose that the sequence can have the specific length(s) now claimed. Explicit support for the specifically claimed limitations (700 base pairs and 701bp-1kB, and 701bp-2.5kB) because the specification must convey to the artisan the claimed subject matter at the time the application was filed. See *Purdue Pharma L.P. v. Faulding Inc.* 230 F.3d 1320, 1326, 56 USPQ2d 1481, 1486 (Fed. Cir. 2000) noting that “with respect In re Ruschig 379 F.2d 990, 154 USPQ 118 (CCPA 1967) that Ruschig makes clear that one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say “here is my invention.” In order to satisfy written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure.” This is the case here, where the specification does not disclose sequences that are “greater than 700 base

Art Unit: 1635

in length”, “701-1000 base pairs” or that are “701 base pairs to 2.5kB in length”, but where the claims have been amended to specifically claim these specific embodiments.

Claims 17-23, 25, 143-147 and 149-162 are included in the rejection because they are dependent claims that encompass all of the embodiments of the independent claims, including the limitations which are new matter.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, the claims are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 76 and 77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 76 has been amended to encompass “a nucleic acid encoding an amino acid sequence... wherein **the amino acid sequence is greater than 700 base pairs in length and**

Art Unit: 1635

further wherein said amino acid sequence encodes a polypeptide that inhibits apoptosis.”

(Emphasis added). It is respectfully pointed out that nucleic acid sequences are comprised of nucleotides which, when double stranded, are arranged as base pairs. Furthermore nucleic acid sequences encode polypeptides. Also, amino acid sequences are comprised of amino acids, not nucleic acids; therefore, amino acid sequences do not comprise any base pairs. Additionally, amino acid sequences do not encode polypeptides. Therefore, the instant claims are indefinite because it is not clear how an amino acid sequence can be “greater than 700 base pairs in length”. It is also unclear how the amino acid sequence can “encode a polypeptide that inhibits apoptosis”. Amending the claim to indicate that the nucleic acid sequence encoding the amino acid sequence is greater than 700 base pairs in length and wherein said nucleic acid sequence encodes a polypeptide that inhibits apoptosis would obviate this rejection. Claim 77 is included in the rejection because it is a dependent claim that encompasses the indefinite limitations of claim 76.

Response to Arguments

Applicant's arguments filed 9/11/2006 have been fully considered.

Applicant's arguments, with respect to the rejection(s) of record have been fully considered and, in view of the amendment to the claims, are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection have been made as indicated above. The new rejections are necessitated by the amendment to the claims.

Allowable Subject Matter

Claims 1, 4-9, 11-14 and 26-28 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

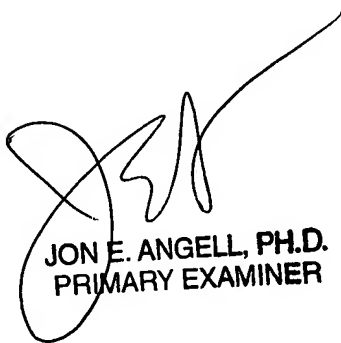
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on 9:00 a.m.- 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1635

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



JON E. ANGELL, PH.D.
PRIMARY EXAMINER